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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,208	07/20/2001	Jiro Hitomi	MM4454	4894

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,208	HITOMI ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2005 and 06 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-24* is/are pending in the application.

4a) Of the above claim(s) *24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-20 and 22-23* is/are rejected.

7)☒ Claim(s) *21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 9/22/05, 2/6/06 and 4/10/-6, is acknowledged.

2. Claims 18-24 are pending.

3. Claim 24 is withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

4. Claims 18-23 are under consideration in the instant application as they read on an antibody with binding affinity to a protein encoded by SEQ ID NO: 12.

5. Claim 21 is objected to under 37 CFR 1.75(c) as being in improper multiple dependent claim because claim 21 depends from claims 19 and 20, wherein claims 19 and 20 are drawn to two different features. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

6. Applicant's IDS, filed 3/28/05, 5/5/05, 8/29/051/30/06and 2/27/06, is acknowledged, however, references 1-2, 4-8, 14, 19 and 21 are crossed out because the English translation of Japanese Documents (1-2, 4-5, 7-8) was not found. Reference 6 is a duplicate of reference 3, reference 19 is a duplicate of reference X cited on the PTO-892 and references 14 and 21 are not appropriate for IDS citation.

7. The following new ground of rejection is necessitated by the amendment submitted 9/22/05 and 2/6/06.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

9. Claims 18-20 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The parenthesis "(or a calcium-binding protein comprising an amino acid sequence encoded by an amino acid sequence shown in SEQ ID NO:1 or 12)" in claim 21 is ambiguous, it is unclear whether the remark in the parenthesis is claimed or not. It is unclear whether the sequences are an essential element of the claim.

B. The recitation "encoded by an amino acid sequence shown in SEQ ID NO: 1 or 12" recited in claims 18 and 21 is indefinite because SEQ ID NO: 1 and 12 are nucleic acid sequences and limited to their nucleic acid components. Applicants have failed to point out how a nucleic acid would comprise an amino acid sequence of SEQ ID NO: 1 and 12.

10. In view of the amendment filed on 9/22/05 and 2/6/06, only the following rejections are remained.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 22 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody with binding affinity to a calcium-binding protein comprising an amino acid sequence encoded by SEQ ID NO: 1 or 12 for diagnosing inflammatory diseases, dermatosis and lung and skin cancer, a method for producing a monoclonal antibody, and a calcium-binging protein assay regent comprising said antibody; does not reasonably provide enablement for a diagnostic agent for inflammatory diseases, "neoplastic diseases", dermatosis or "blood diseases", which comprises an antibody of claim 18, in claim 22. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons set forth in the previous Office Action mailed 3/17/05.

Applicant's arguments, filed 9/22/05, have been fully considered, but have not been found convincing.

Applicant has not address this issue therefore the Examiner reiterate the rejection again.

The scope of claim 22 is that the claimed antibodies would diagnose all and every blood diseases or neoplastic diseases. However, sickle cell disease is a common inherited red blood disorder which cannot be diagnosed using the claimed antibody because the said antibody does not detect the presence of sickle haemoglobin, neither does it distinguish between sickle cell trait and sickle cell disorders. Similarity, hemophilia, Huntington's disease, cystic fibrosis, phenylketonuria, blood pressure, among others cannot be diagnose using the claimed antibody. Further, it is unpredicted whether the claimed antibody would diagnose all and every neoplastic diseases. Yamamura et al (1996) teach that CAAF1 gene expression may be altered in malignant neoplasms. Further study is required to determine whether CAAF1 is involved in malignant transformation. Furthermore, besides the squamous epithelial carcinoma of the lung and skin cancer, the specification fails to provide guidance on how to diagnose other non-epithelial cell derived neoplastic diseases such as sarcoma (mesenchymal), or fibroma (a benign neoplasm of

fibroblast origin) because the specification does not disclose a nexus between such diseases and a change in the expression of BAAF1.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 18-19 and 22-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Guignard *et al* (European Journal of Clinical Investigation, Vol:24, Supl. 2, pp.211, 1994), as is evidenced by Guignard *et al* (July 1995), Yamamura et al and the specification on page 2 lines 7-35 for the same reasons set forth in the previous Office Action mailed 3/17/05.

Applicant's arguments, filed 9/22/05, have been fully considered, but have not been found convincing.

Applicant submits that Guignard et al reference describes polyclonal antibodies to MRP-8 cross-reacts with p6, and the Guignard et al(1995) describes that an N-terminal sequence of the p6 is the same as that of CAAF1. Applicant concludes that references do not describe an antibody raised against CAAF1 (emphasis added by Applicant). Accordingly, antibody of the present invention is clearly not taught in the Guignard et al reference.

However, since p6 is CAAF1, as is evidenced byYamamura *et al*, then the referenced MRP-8 antibody binds CAAF1. Further, an antibody "cross-reacts", i.e., binds to more than one protein sequence base on antigens with homolgous amino acid residues. Further, once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process. Antibodies are antibodies irrespective of how they are made.

15. Claim 18-20 and 22-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kelly *et al* (J. Patho. 1989), as is evidenced by Guignard *et al* (Immunol Cell Biol. 1996 Feb;74(1):105-7), Guignard *et al* (July 1995) Yamamura et al and the specification on page 2 lines 7-35 for the same reasons set forth in the previous Office Action mailed 3/17/05.

Applicant's arguments, filed 9/22/05, have been fully considered, but have not been found convincing.

Applicant argues that the reactivity of the referenced antibody is mere cross-reactivity. Applicant points out that the MAC387 does not react with the p6 protein in Figure 1 of Guignard et al (1995).

However, an antibody "cross-reacts", i.e., binds to more than one protein sequence based on antigens with homolgous amino acid residues. Contrary to applicant assertion, in figure 1b of

Guignad et al (1995) Mac 387 weakly recognizes p6b (i.e. binds to) (see page 397, 2nd col., last sentence of paragraph 1 in particular).

16. No claim is allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 23, 2006

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